Frequently Asked Questions

Magnetic Resonance Imaging (MRI) in Medicare Patients with Cardiovascular Implantable Electronic Devices (CIEDs)

INTRODUCTION

In April 2018, the Centers for Medicare and Medicaid Services (CMS) published a national coverage decision (NCD) for MRIs in patients with Cardiovascular Implantable Electronic Devices. The NCD states that "magnetic resonance imaging (MRI) for Medicare beneficiaries with an implanted pacemaker (PM), implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy pacemaker (CRT-P), or cardiac resynchronization therapy defibrillator (CRT-D) is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member […] under certain circumstances."

This guide provides answers to Frequently Asked Questions regarding MRIs for Medicare beneficiaries with an implanted pacemaker, implantable cardioverter defibrillator (ICD), cardiac resynchronization therapy pacemaker (CRT-P), or cardiac resynchronization therapy defibrillator (CRT-D), henceforth referred to as Cardiovascular Implantable Electronic Devices (CIEDs). For additional support, Abbott offers a reimbursement hotline that provides live coding and reimbursement information from dedicated reimbursement specialists. Coding and reimbursement support is available from 8 a.m. to 5 p.m. central time, Monday through Friday at (855) 569-6430 or hce@abbott.com. Coding and reimbursement assistance is provided subject to the disclaimers set forth in this guide.

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FREQUENTLY ASKED QUESTIONS

Q1: Under what circumstances does Medicare cover an MRI for a patient with a Cardiovascular Implantable Electronic Device (i.e., pacemaker, ICD, or cardiac resynchronization therapy device)?

According to the Medicare decision memo, an MRI is covered for:

1. Patients with a CIED that has FDA labeling for use in an MRI environment (referred to as "MRI conditional" devices/labeling); **and**
2. Patients with a CIED that does not have FDA labeling for use in an MRI environment (referred to as "MRI nonconditional" devices/labeling) under certain conditions (outlined under Q2 below).[1]

Q2: Under what conditions will Medicare cover MRIs for patients with an implanted CIED that is *not* labeled for use in an MRI environment?

Medicare will cover MRI scans for beneficiaries with an implanted pacemaker, ICD, or cardiac resynchronization therapy device that does not have FDA labeling specific to use in an MRI environment under the following conditions:

a) MRI field strength is 1.5 Tesla using Normal Operating Mode;
b) The implanted pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy pacemaker, or cardiac resynchronization therapy defibrillator system has no fractured, epicardial, or abandoned leads;
c) The facility has implemented a checklist which includes the following:
   - patient assessment is performed to identify the presence of an implanted pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy pacemaker, or cardiac resynchronization therapy defibrillator;
   - prior to the MRI scan, benefits and harms of the MRI scan are communicated with the patient or the patient's delegated decision-maker;
   - prior to the MRI scan, the implanted pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy pacemaker, or cardiac resynchronization therapy defibrillator is interrogated and programmed appropriately during the scan based on device and patient characteristics;
   - a qualified physician, nurse practitioner or physician assistant with expertise with implanted pacemakers, implantable cardioverter defibrillators, cardiac resynchronization therapy pacemakers, or cardiac resynchronization therapy defibrillators must directly supervise as defined in 42 CFR § §410.28 and 410.32;
   - patients are observed throughout the MRI scan via visual and voice contact and monitored with equipment to assess vital signs and cardiac rhythm;
   - an advanced cardiac life support provider must be present for the duration of the scan;
   - a discharge plan that includes before being discharged from the hospital/facility, the patient is evaluated and the implanted pacemaker, implantable cardioverter defibrillator, cardiac resynchronization therapy pacemaker, or cardiac resynchronization therapy defibrillator is reinterrogated immediately after the MRI scan to detect and correct any abnormalities that might have developed during the MRI.[1]

Q3: Do patients with CIEDs that are labeled for use in an MRI environment need to meet the criteria listed in Q2 for the MRI to be covered by Medicare?

No. Only patients with MRI nonconditional CIEDs are required to meet the criteria for Medicare coverage of an MRI scan. Please note that medical necessity must be documented for all patients receiving an MRI and the MRI scan must be performed according to approved labeling.

Q4: Are MRIs for patients with 'combination' device systems (systems that combine lead and battery components from various manufacturers) covered by Medicare?

Yes, MRIs for patients with combination device systems are covered by Medicare if they meet the criteria outlined in Q2 above. Device systems that combine individual lead and device components from various manufacturers are not labeled for use in an MRI environment, even if the individual components (leads/battery) have MRI conditional labeling.[4] For this reason, to be covered by Medicare, MRIs in patients with these combination device systems must meet the criteria for an MRI nonconditional device.

Q5: Are 3T MRIs for patients with CIEDs covered by Medicare?

It depends on whether the patient's CIED has 3T-specific MRI labeling. If the patient has a CIED with 3T-specific MRI labeling, Medicare will cover the 3T MRI. If the patient has a CIED with 1.5T-specific MRI labeling, Medicare will cover a 1.5T MRI only, not a 3T MRI. If the patient has a CIED that does not have MRI labeling (3T or 1.5T) the MRI must meet the criteria outlined above, including a) MRI field strength is 1.5 Tesla using Normal Operating Mode.

Q6: Does this policy apply to other payers as well as Medicare?

No, this policy only applies to Medicare. Other payers may or may not adopt this policy. Abbott recommends you consult with your payers to understand their MRI coverage policies, especially requirements for prior authorization for all MRI scans. Also, please note that local Medicare Administrative Contractors (MACs) may have additional coverage criteria as published in Local Coverage Determinations or articles.

Q7: What does CMS mean by "directly supervise" in the checklist item "a qualified physician, nurse practitioner or physician assistant with expertise with implanted pacemakers, implantable cardioverter defibrillators, cardiac resynchronization therapy pacemakers, or cardiac resynchronization therapy defibrillators must directly supervise"?

According to the Medicare Benefit Policy Manual, "direct supervision" means that the "physician or non-physician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. The physician is not required to be present in the room where the procedure is performed or within any other physical boundary as long as he or she is immediately available."[2]

Q8: Do MRI scans need to be part of a clinical study to be covered by Medicare?

No. Medicare discontinued the Coverage with Evidence Development (CED) requirement in 2018, meaning MRI scans do not need to part of a clinical study to be covered by Medicare.

Q9: How does a physician bill Medicare for the device programming, interrogation, and direct supervision required during a MRI scan for a patient with a device that is not labeled for use in a MRI environment?

Current guidance is for the performing physician to utilize the in-person device interrogation and/or programming codes for this service. For additional information on device interrogation and programming codes, please consult the Abbott *Cardiac Device Monitoring Services* guide at: https://www.cardiovascular.abbott/us/en/hcp/reimbursement/crm.html.

To report physician supervision of the MRI scan, Chapter 13 of the Medicare Claims Processing Manual states that "radiologic supervision and interpretation (S&I) codes are used to describe the personal supervision of the performance of the radiologic portion of a procedure by one or more physicians and the interpretation of the findings. In order to bill for the supervision aspect of the procedure, the physician must be present during its performance. This kind of personal supervision of the performance of the procedure is a service to an individual beneficiary and differs from the type of general supervision of the radiologic procedures performed in a hospital for which A/B MACs (A) pay the costs as physician services to the hospital. The interpretation of the procedure may be performed later by another physician. In situations in which a cardiologist, for example, bills for the supervision (the "S") of the S&I code, and a radiologist bills for the interpretation (the "I") of the code, both physicians should use a "-52" modifier indicating a reduced service, e.g., only one of supervision and/or interpretation. Payment for the fragmented S&I code is no more than if a single physician furnished both aspects of the procedure."[3]

Q10: Who can I contact for more information?

Call our Reimbursement Hotline at (855) 569-6430, available 8-5pm CT, or email hce@abbott.com.

REFERENCES

1. Decision Memo for Magnetic Resonance Imaging (MRI) (CAG-00399R4) Decision Summary https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=289
2. CMS Transmittal 169, CMS Manual System, Pub 100-02 Medicare Benefit Policy https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r169bp.pdf
3. Medicare Claims Processing Manual. Chapter 13 - Radiology Services and Other Diagnostic Procedures (Rev. 4267, 03-27-19) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c13.pdf
4. 2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices. https://www.hrsonline.org/clinical-resources/2017-hrs-expert-consensus-statement-magnetic-resonance-imaging-and-radiation-exposure-patients

Abbott
One St. Jude Medical Dr., St. Paul, MN 55117, USA, Tel: 1 651 756 2000